

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-28 were pending in this application when last examined.

Kindly clarify the status of claim 12. In items 4(a) and 6 on page 1 and in the 4th paragraph on page of the Office Action, claims 1-4, 7-11, 15-18 and 21-26 were incorrectly listed as the examined and rejected claims, because claim 12 is omitted therefrom and there is no indication that this claim was withdrawn. Moreover, claim 12 is directed to the elected species (i.e., *Tricholoma matsutake*) and the invention of elected Group I (claims 1-12 and 15-26). Thus, claim 12 should be examined with the elected invention. Accordingly, claims 1-4, 7-12, 15-18 and 21-26 should be the correct listing of the examined claims.

Claims 5, 6, 13, 14, 19, 20, 27 and 28 were withdrawn as non-elected subject matter.

Claims 1 and 15 are amended to recite "a biologically pure culture of *Tricholoma*" as suggested by the Examiner. Support can be found at page 7, lines 5-7.

Therefore, no new matter has been added by this amendment.

The specification is amended to reflect the deposit information and to indicate that the strain was deposited under the terms of the Budapest Treaty as required by the Examiner. No new matter has been added by this amendment.

II. NON-STATUTORY SUBJECT MATTER

On page 3 of the Office Action, claims 1-4, 7-11, 15-18 and 21-25 were rejected under 35 U.S.C. § 101 on the basis that the claims are directed to non-statutory subject matter, i.e., products of nature.

This rejection is respectfully traversed as applied to the amended claims.

As noted above, independent claims 1 and 15 are amended to recite “a biologically pure culture of *Tricholoma*” as suggested by the Examiner.

In view of this amendment, the rejection of claims 1-4, 7-11, 15-18 and 21-25 under 35 U.S.C. § 101 is untenable and should be withdrawn.

III. OBJECTION TO THE SPECIFICATION & ENABLEMENT & WRITTEN DESCRIPTION REJECTIONS - BIOLOGICAL DEPOSIT

On pages 3-5 of the Office Action, the specification was objected to and claims 1-4, 7-11, 15-18 and 21-26 were rejected under 35 U.S.C. § 112, first paragraph, as lacking an enabling disclosure and written description support for the claimed strain of *Tricholoma*. On pages 6-7, the specification is objected regarding the deposit.

This rejection is respectfully traversed.

Attached herewith are a Declaration of Microorganism Availability and a deposit receipt for *Ticholoma matsutake* strain FERM BP-7304. These documents are evidence that *Ticholoma matsutake* strain FERM BP-7304 was deposited under the terms of the Budapest Treaty.

Pursuant to 37 CFR § 1.808, (1) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Director to be entitled thereto, and (2) subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

The specification is amended to reflect the deposit information as required.

Therefore, it is respectfully submitted that the specification and the deposit therein comply with the deposit rules.

Furthermore, it is respectfully submitted the numerous strains of *Ticholoma matsutake*, such as listed on pages 5-6 of the disclosure, are known and publically available and could be used as the starting materials to arrive at the claimed invention without undue experimentation.

In view of the above, the objection to the specification, the enablement rejection and the written description rejection of claims 1-4, 7-11, 15-18 and 21-26 under 35 U.S.C. § 112, first paragraph are untenable and should be withdrawn.

IV. WRITTEN DESCRIPTION REJECTION

On page 7 of the Office Action, claim 26 was rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description support for every known antibiotic.

This rejection is respectfully traversed.

It is respectfully submitted that the disclosure need not provide written support for “every known antibiotic.”

Instead, the test for sufficiency of written description is whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession at the time of filing of the subject matter which is claimed. See M.P.E.P. § 2163, I, 2100-159, 1st column, 2nd paragraph.

This test may be satisfied by: (1) a reduction to practice; (2) a reduction to drawings/chemical formulas; (3) a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, concise and exact terms; (4) a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure sufficient; (5) a sufficient description of a representative number of species; or (6) a combination of the above, sufficient to show Applicants were in possession of the invention. See M.P.E.P. § 2163, 2100-170 to 2100-174, II, A, 3 a(i)-(ii).

In this case, the specification at page 36, lines 19-27 indicates that antibiotics may be incorporated into the infection preventive or therapeutic agent of the claims. The exemplified antibiotics are vancomycin, penicillin and tetracycline. Moreover, it is indicated that the antibiotic may be properly determined in accordance with the kind of relevant infectious disease

to treated. In other words, one of skill in the art selects the antibiotic from those known in the art which is specific to the infectious disease to be treated. Thus, it is respectfully submitted that the specification provides a reduction to practice, a sufficient description of a representative number of species of antibiotics and a disclosure of relevant identifying characteristics.

Thus, in view of the above, the rejection of claim 26 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

V. ANTICIPATION REJECTION

On page 8 of the Office Action, claims 1-3, 7-11, 15-17 and 21-25 were rejected under 35 U.S.C. § 102(b) as anticipated by Shimazono (JP 53162990, English Abstract).

This rejection is respectfully traversed as applied to the amended claims.

To anticipate a claim, a cited prior art reference must teach each and every element of the claimed invention. M.P.E.P. § 2131.01.

The claims are directed to a preventive or therapeutic agent for infection(s) with a pathogenic microorganism, containing a biologically pure culture of a member of basidiomycetes belonging to genus *Tricholoma* or an extract thereof.

As described at page 2, line 15 to page 4, line 5 in the disclosure, it has not yet been reported that *Tricholoma matsutake* or basidiomycetes belonging to *Tricholoma*, which is a genus of *Tricholoma matsutake*, has excellent preventive or therapeutic effects for fighting the onset and/or the progression of infections with pathogenic bacteria, such as *Pseudomonas aeruginosa* and *Listeria monocytogenes*.

The present Applicants discovered that *Tricholoma matsutake* or basidiomycetes belonging to *Tricholoma*, which is a genus of *Tricholoma matsutake*, has excellent preventive or therapeutic effects for fighting infections with pathogenic bacteria, such as *Pseudomonas aeruginosa* and *Listeria monocytogenes*.

There is no teaching or suggestion of this in Shimazono (JP 53162990). Instead, Shimazono (JP 53162990) merely discloses a method of incubating *Mycorrhiza*-forming fungi,

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which comprises inoculating the fungi belonging to *Tricholoma* in a medium containing 3 w/v % or more of starch, and incubating under an air flow, thereby to obtain large quantities of mycelia of the fungi.

In view of the above, it is respectfully submitted that the rejection of claims 1-3, 7-11, 15-17 and 21-25 under 35 U.S.C. § 102(b) is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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ATTACHMENTS

1. Declaration of Microorganism Deposit;
2. Deposit Receipt for *Ticholoma matsutake* strain FERM BP-7304.